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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,439

02/26/2004

Scott D. Ganz

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EXAMINER

SCHILLINGER, ANN M

ART UNIT

PAPER NUMBER

3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/789,439

Applicant(s)

GANZ ET AL.

Examiner

Ann Schillinger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 93-122 and 149-151 is/are pending in the application.
- 4a) Of the above claim(s) 1-92 and 123-148 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 93-122 and 149-151 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/29/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected 1-92 and 123-148, there being no allowable generic or linking claim..

Election was made **without** traverse in the reply filed on 12/26/2006.

Applicant's election without traverse of claims 93-122 and 149-151 in the reply filed on 12/26/2006 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

Claim 103 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 93-96, 98-102, 104-120, and 150 are rejected under 35 U.S.C. 102(b) as being anticipated by Tormala et al. (U.S. Pat. No. 5,084,051). Tormala et al discloses the following of claim 93: a bone graft suitable to fill a recess around an implant base, wherein the bone graft comprises rigid porous synthetic material (col. 2, lines 28-34; col. 18, lines 19-24).

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Tormala et al discloses the following of claim 94: the bone graft of claim 93, wherein the bone graft is pre-formed to a desired shape (see Figures 4, 6a-6c, 7a-7d).

Tormala et al discloses the following of claim 95: the bone graft of claim 93, wherein the bone graft comprises at least two separate pieces (1, 2) which together provide a desired shape.

Tormala et al discloses the following of claim 96: the bone graft of claim 93, wherein the bone graft comprises a central hole (hole where label "2" is located on Figure 7b).

Tormala et al discloses the following of claim 98: the bone graft of claim 93, wherein the bone graft is substantially axisymmetric (an axis through the top of Figures 7a-7d would have axisymmetric bone grafts).

Tormala et al discloses the following of claim 99: the bone graft of claim 93, wherein the bone graft is non-axisymmetric (an axis through the top of Figure 3 (right side) would have non-axisymmetric bone grafts).

Tormala et al discloses the following of claim 100: the bone graft of claim 93, wherein the implant has external shape and dimensions which are chosen based on the shape and dimensions of a region of deteriorated or resorbed bone at a particular site in a particular patient (col. 4, lines 67 through col. 5, lines 12).

Tormala et al discloses the following of claim 101: the bone graft of claim 330, wherein the dimensions of the region of deteriorated or resorbed bone are determined radiographically (col. 18, lines 37-39).

Tormala et al discloses the following of claim 102: the bone graft of claim 93, wherein the bone graft comprises a matrix of particles joined to each other forming a three-dimensionally interconnected network (col. 11, lines 2-9).

Tormala et al discloses the following of claim 104: the bone graft of claim 102, wherein the matrix has a porosity between approximately 0.2 and approximately 0.6 (col. 13, lines 28-30).

Tormala et al discloses the following of claim 105: the bone graft of claim 93, wherein the bone graft comprises nonresorbable material (col. 6, lines 41-42).

Tormala et al discloses the following of claim 106: the bone graft of claim 93, wherein the bone graft comprises hydroxyapatite (col. 18, lines 19-24).

Tormala et al discloses the following of claim 107: the bone graft of claim 93, wherein the bone graft comprises resorbable material (col. 6, lines 41-42).

Tormala et al discloses the following of claim 108: the bone graft of claim 93, wherein the bone graft comprises both nonresorbable and resorbable substances (col. 16, lines 15-20).

Tormala et al discloses the following of claim 109: the bone graft of claim 93, further comprising channels which go into an interior (in Figure 2c, channels that screws, R, go through).

Tormala et al discloses the following of claim 110: the bone graft of claim 93, further comprising channels or patterns on a surface (see Figure 3 (right side)).

Tormala et al discloses the following of claim 111: the bone graft of claim 93, wherein the bone graft comprises a surface having a surface geometry (1) which is different from a geometry at an interior (2) (see Figure 3 (right side)).

Tormala et al discloses the following of claim 112: the bone graft of claim 93, wherein the bone graft comprises a surface having a surface composition which is different from a composition at an interior (see Figure 3; col. 10, lines 39-41).

Tormala et al discloses the following of claim 113: the bone graft of claim 93, wherein the bone graft comprises a surface having a surface geometry suitable to face natural bone (see Figure 2c).

Tormala et al discloses the following of claim 114: the bone graft of claim 93, wherein the bone graft comprises a surface having a surface composition suitable to face natural bone (see Figure 2c; col. 10, lines 40-43)

Tormala et al discloses the following of claim 115: the bone graft of claim 93, further comprising osteoconductive or osteoinductive substances (col. 19, lines 56-61; col. 20, lines 6-8).

Tormala et al discloses the following of claim 116: the bone graft of claim 93, further comprising substances from a patient's own blood or other biological substances or demineralized bone matrix (col. 1, lines 49-55; col. 5, lines 65 through col. 6, line 4).

Tormala et al discloses the following of claim 117: the bone graft of claim 93, further comprising a polymer (col. 4, lines 19-21; see Table 1).

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Tormala et al discloses the following of claim 118: the bone graft of claim 117, wherein the polymer is a comb polymer (see Table 1, where polyurethane is listed).

Tormala et al discloses the following of claim 119: the bone graft of claim 117, wherein the polymer is resorbable (see Table 1).

Tormala et al discloses the following of claim 120: the bone graft of claim 117, wherein the polymer is non-resorbable (col. 1, lines 45-53).

Tormala et al discloses the following of claim 150: the bone graft of claim 93, wherein the bone graft comprises tricalcium phosphate (col. 1, line 21).

Claim 151 is rejected under 35 U.S.C. 102(b) as being anticipated by Sherwood et al. (U.S. Pat. No. 6,454,811). Boyce et al. discloses the following of claim 151: a bone graft for filling a recess around an endosseous implant base, said bone graft being manufactured by a method which comprises: spreading successive layers of a powder and three dimensionally printing an article to at least approximately the dimensions of the recess around the endosseous implant base.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 97 and 149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Kuslich et al. (U.S. Pat. No. 5,899,908). Tormala et al. disclose the

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invention substantially as claimed, however, Tormala et al. has holes in some implant, but does not disclose a bone graft with an inside diameter larger the outside diameter. Kuslich et al. teaches the hole (16, 17) and an inside diameter greater than the outside diameter by less than about 0.5 mm in col. 13, lines 18-19, 41-42, and col. 7, lines 41-48, 52-59, for the purpose of enabling the implant to more easily receive tools that will properly insert the implant into the patient (col. 5, lines 9-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the inside diameter larger than the outside diameter in order to allow the implant receive tools that will properly insert the implant into the patient.

Tormala et al. disclose the invention substantially as claimed, however, Tormala et al does not disclose adapting the bone graft to receive a tool. Kuslich et al. teaches adapting the bone graft for receiving a tool in col. 2, lines 20-27 and col. 4, lines 61-67 for the purpose of more easily using the tool to insert the bone graft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to adapt the bone graft to receive a tool in order to more easily use the tool to insert the bone graft.

Claims 103 and 122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Sherwood et al. (U.S. Pub. No. 2003/0114936). Tormala et al. disclose the invention substantially as claimed, however, Tormala et al does not disclose a pore volume as a function of pore size with a mode between 10 and 25 micrometers. Sherwood et al. teaches pore volume as a function of pore size in paragraph 0077 for the purpose of controlling the flow of nutrients to new cells and the surface area available for attachment (paragraph 0066). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention

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was made to make pore volume a function of pore size in order to control both the flow of nutrients to new cells and the surface area available for attachment.

Tormala et al. disclose the invention substantially as claimed, however, Tormala et al does not disclose three dimensional printing to formulate the pores on the bone graft. Sherwood et al. teaches three dimensional printing for the purpose of better controlling the pore size (paragraphs 0051, 0052). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use three dimensional printing to make the pores in order to better control the pore size.

Claim 121 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Ducheyne et al. (U.S. Pat. No. 5,591,453). Tormala et al. disclose the invention substantially as claimed, however, Tormala et al does not disclose making sure the bone graft is sterile. Ducheyne et al. teaches sterilizing the graft in col. 1, lines 24-35 for the purpose of making material non-toxic and non-immunogenic. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to sterilize the bone graft in order to make the material non-toxic and non-immunogenic.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
February 7, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER